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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,006	07/18/2003	Val Krukonis	07678/116002	4588

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

LOPEZ, CARLOS N

ART UNIT	PAPER NUMBER
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1731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/623,006

Applicant(s)

KRUKONIS ET AL.

Examiner

Carlos Lopez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Pre-Appeal Brief Response

Applicant's pre-appeal request has been considered. The finality of the previous office action is withdrawn. Applicant in arguing against the Garner references raises new 112 1st and 2nd Paragraph issues that are detailed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The processing conditions as noted in Tables I-IV are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

In the pre-appeal conference and in applicant's response dated 9/26/05 applicant establishes that the mere act of contacting tobacco with a sub-critical fluid does not necessarily extract the desired tobacco constituents. In particular, applicant argues that just contacting the tobacco with a sub-subcritical fluid does not establish that the claimed effect will occur.

Applicant, in the response dated 9/26/05 and recently in applicant's pre-appeal conference, implies that data shown in table 3 such as pH and moisture content are process parameters that are necessary to control the amount of constituents removed from tobacco.

However, none of the claims recite a pH and/or moisture content that is deemed essential in order to remove the desired constituents of the tobacco as argued by applicant.

Currently, the claims merely require contact of a sub-critical carbon dioxide or a hydrocarbon in order to achieve removal of a tobacco constituent. Yet, applicant in arguing against Garner notes that other process parameters need to be considered in order to obtain the claimed desired effect. Hence, Applicant's arguments are deemed as supporting that the specific parameters noted in tables 1-4 are necessary to achieve the claimed effect.

If just merely contacting a tobacco with a sub-critical fluid does not provide for the claimed effects as argued by applicant, and done so by Garner, the same standard would apply for the instant claimed invention.

The claimed inventions do not recite the alleged temperature, pressure, pH, and moisture contents that applicant seems to allege are necessary to provide for the claimed effect.

In fact, claims 2-5 only require a sub-critical fluid (water at room temperature) contacting the tobacco to achieve the claimed constituent removal. But, claims 2-5 do not disclose said process parameters that would achieve the claimed effect as argued against Garner. In arguing against Garner, applicant is establishing that its very own claims that do not include essential subject matter to practice the claimed invention.

In conclusion, arguing against Garner by establishing that other process parameters are necessary to achieve the removal of a constituent, applicant seriously raises the above noted 112 1st paragraph issue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. If the above noted process parameters are deemed as necessary to achieve the claimed effect as implied by applicant, it is unclear in reciting the claimed effect, to which distinct and particular process parameter is applicant seeking patent protection.

The specification recites, moisture, pH, pressure, and temperature as process parameters and as implied by applicant that said process parameters need to be considered in order to achieve the claimed effect such as a particular constituent removal or removal of one constituent in greater amounts than another.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos Lopez whose telephone number is 571.272.1193. The examiner can normally be reached on Mon.-Fri. 8am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571.272.1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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